

B5
35. (Amended twice) The method of claim 101, wherein the pharmaceutical comprises at least one of sildenafil citrate, pentoxifylline, yohimbine, apomorphine, alprostadil, papavaerine, or phentolamine, or a combination, salt, or enantiomer thereof.

36. (Amended twice) The method of claim 101, wherein the pharmaceutical is sildenafil citrate.

B6
41. (Amended twice) The method of claim 101, wherein the composition comprises about 1.0% w/w of testosterone.

42. (Amended twice) The method of claim 101, wherein the composition comprises about 0.5% to about 1.0% w/w isopropyl myristate.

B7
45. (Amended twice) The method of claim 101, wherein the subject is hypogogadal.

B8
48. (Amended twice) The method of claim 101, wherein the subject is a man, and the composition is administered to an area of skin selected from the group consisting of arm, shoulder, abdomen, back, and thigh.

B8
49. (Amended twice) The method of claim 101, wherein the composition is administered to the subject in an amount to deliver to the skin about 25 mg to about 100 mg of testosterone per day.

B9
57. (Amended) The method of claim 101, wherein the pharmaceutical is apomorphine.

58. (Amended) The method of claim 101, wherein the composition is administered to the skin of the subject in an amount from about 2.5 g/day to about 10.0 g/day.

B9 cont

59. (Amended) The method of claim 101, wherein the composition administered to the subject achieves a maximum serum testosterone concentration at about 16 hours to about 22 hours after administration of the composition.

B10

62. (Amended) The method of claim 101, wherein the composition is administered at least once per day.

B11

64. (Amended) The method of claim 63, wherein the percutaneous administration is to same site for approximately 7 days.

B12

75. (Amended) The method of claim 101, wherein the composition comprises about 0.25% to about 5% w/w testosterone.

76. (Amended) The method of claim 101, wherein the composition comprises about 1% w/w testosterone.

77. (Amended) The method of claim 101, wherein the composition comprises about 0.1% w/w testosterone.

78. (Amended) The method of claim 101, wherein the gelling agent comprises polyacrylic acid.

79. (Amended) The method of claim 78, wherein the polyacrylic acid is in an amount of about 0.9% w/w of the composition.

80. (Amended) The method of claim 101, wherein the composition comprises about 0.25% to about 2.5% w/w isopropyl myristate.

81. (Amended) The method of claim 101, wherein the composition comprises about 0.5% w/w isopropyl myristate.

B12
cnt

82. (Amended) The method of claim 101, wherein the composition comprises about 40% to about 90% w/w ethanol.

B13

83. (Amended) The method of claim 101, wherein the composition comprises about 72.5% w/w ethanol.

88. (Amended) The method of claim 101, wherein the pharmaceutical is a phosphodiesterase inhibitor.

89. (Amended) The method of claim 88, wherein the phosphodiesterase inhibitor is at least one of type III, type IV, or type V, and mixtures thereof.

90. (Amended) The method of claim 89, wherein the phosphodiesterase inhibitor is type V.

91. (Amended) The method of claim 88, wherein the phosphodiesterase inhibitor is administered to the subject in about a 50 mg oral dose.

92. (Amended) The method of claim 88, wherein the phosphodiesterase inhibitor is administered about 20 minutes to about 60 minutes before sexual intercourse.

93. (Amended) The method of claim 88, wherein the phosphodiesterase inhibitor is administered in the form of at least one of a salt, ester, amide, or prodrug, and mixtures thereof.

B14

97. (Amended) The method of claim 101, wherein the pharmaceutical is administered about 20 minutes to about 60 minutes before sexual intercourse.

98. (Amended) The method of claim 101, wherein the composition and the pharmaceutical are components of a kit.

*B1st
cont*

99. (Amended) The method of claim 98, wherein the kit further comprises a set of instructions.

B1S *Sch C*

III. Addition of New Claims

Please add the following claims as follows:

101. (New) A method for improving the efficacy of a pharmaceutical useful for treating erectile dysfunction in a male subject, comprising:

percutaneously administering to an area of skin of the subject a pharmaceutically effective amount of a composition, comprising:

- a. about 0.1% to about 10% testosterone;
- b. about 30% to about 98% alcohol comprising ethanol, or isopropanol;
- c. about 0.1% to about 5% isopropyl myristate;
- d. about 1% to about 5% sodium hydroxide; and
- e. about 0.1% to about 5% gelling agent; and

administering the pharmaceutical to the subject;
wherein the percentages are weight to weight of the composition.

102. (New) A method for improving the efficacy of a pharmaceutical useful for treating erectile dysfunction in a male subject, comprising:

percutaneously administering to the subject a pharmaceutically effective amount of a composition, comprising:

- a. about 0.1% to about 10% testosterone;
- b. about 30% to about 98% alcohol comprising ethanol, or isopropanol;
- c. about 0.1% to about 5% isopropyl myristate;
- d. about 1% to about 5% sodium hydroxide; and
- e. about 0.1% to about 5% gelling agent; and

administering the pharmaceutical to the subject;
wherein the amount of the composition administered to the subject is sufficient to achieve an erection for sexual intercourse in the subject; and the percentages are weight to weight of the composition.

103. (New) The method of claim 102, wherein the subject is eugonadal.

104. (New) The method of claim 102, wherein the pharmaceutical is a phosphodiesterase inhibitor.

*B15
cont*

105. (New) The method of claim 104, wherein the phosphodiesterase inhibitor is at least one of type III, type IV, or type V, and mixtures thereof.

106. (New) The method of claim 105, wherein the phosphodiesterase inhibitor is type V.

107. (New) The method of claim 104, wherein the phosphodiesterase inhibitor is administered to the subject in about a 50 mg oral dose.

108. (New) The method of claim 104, wherein the phosphodiesterase inhibitor is administered about 20 minutes to about 60 minutes before sexual intercourse.

109. (New) The method of claim 104, wherein the phosphodiesterase inhibitor is administered in the form of at least one of a salt, ester, amide, or prodrug, and mixtures thereof.

110. (New) The method of claim 102, wherein the pharmaceutical comprises at least one of sildenafil citrate, pentoxifylline, yohimbine, apomorphine, alprostadil, papavaerine, or phentolamine, or a combination, salt, or enantiomer thereof.

111. (New) The method of claim 110, wherein the pharmaceutical is sildenafil citrate.

112. (New) The method of claim 110, wherein the pharmaceutical is apomorphine.

113. (New) The method of claim 102, wherein the pharmaceutical is administered about 20 minutes to about 60 minutes before sexual intercourse.

114. (New) The method of claim 102, wherein the composition comprises about 1.0% w/w of testosterone.

115. (New) The method of claim 102, wherein the composition comprises about 0.5% to about 1.0% w/w isopropyl myristate.

*PIS
Cont*

116. (New) The method of claim 102, wherein the subject is hypogadal.

117. (New) The method of claim 102, wherein the subject is a man, and the composition is administered to an area of skin selected from the group consisting of arm, shoulder, abdomen, back, and thigh.

118. (New) The method of claim 102, wherein the composition is administered to the subject in an amount to deliver to the skin about 25 mg to about 100 mg of testosterone per day.

119. (New) The method of claim 102, wherein the composition is administered to the skin of the subject in an amount from about 2.5 g/day to about 10.0 g/day.

120. (New) The method of claim 102, wherein the composition administered to the subject achieves a maximum serum testosterone concentration at about 16 hours to about 22 hours after administration of the composition.

121 (New) The method of claim 102, wherein in the composition is administered at least once per day.

122. (New) The method of claim 121, wherein the percutaneous administration is to same site for approximately 7 days.

123. (New) The method of claim 102, wherein the composition comprises about 0.25% to about 5% w/w testosterone.

124. (New) The method of claim 102, wherein the composition comprises about 1% w/w testosterone.

125. (New) The method of claim 102, wherein the composition comprises about 0.1% w/w testosterone.

*B15
Cmt*
126. (New) The method of claim 102, wherein the gelling agent comprises polyacrylic acid.

127. (New) The method of claim 126, wherein the polyacrylic acid is in an amount of about 0.9% w/w of the composition.

128. (New) The method of claim 102, wherein the composition comprises about 0.25% to about 2.5% w/w isopropyl myristate.

129. (New) The method of claim 102, wherein the composition comprises about 0.5% w/w isopropyl myristate.

130. (New) The method of claim 102, wherein the composition comprises about 40% to about 90% w/w ethanol.

131. (New) The method of claim 102, wherein the composition comprises about 72.5% w/w ethanol.

132. (New) The method of claim 102, wherein the composition and the pharmaceutical are components of a kit.

133. (New) The method of claim 132, wherein the kit further comprises a set of instructions.

134. (New) The method of claim 102, wherein the composition is the form of a gel.

135. (New) The method of claim 134, wherein the gel is in a dosage form and the dosage form weighs about 1.0 grams to about 10 grams.

*B15
cont*

136. (New) The method of claim 134, wherein the gel is in a dosage form and the dosage form weighs about 2.5 grams to about 7.5 grams.

137. (New) The method of claim 134, wherein the gel is in a dosage form and the dosage form weighs about 5.0 grams.

138. (New) The method of claim 102, wherein the testosterone comprises an enantiomer, a racemic mixture, a derivative, a base, or a salt thereof.

139. (New) The method of claim 102, wherein the composition is provided to the subject for daily administration in a 5 g, 7.5 g, or 10 g dose.

140. (New) The method of claim 139, wherein the dose delivers about 1 mg to about 100 mg of testosterone to the skin.

141. (New) The method of claim 139, wherein the dose is a 5 g dose delivering about 1 mg to about 50 mg of testosterone to the skin.

142. (New) The method of claim 139, wherein the dose is a 7.5 g dose delivering about 1 mg to about 75 mg of testosterone to the skin.

143. (New) The method of claim 139, wherein the dose is a 10 g dose delivering about 10 mg to about 100 mg of testosterone to the skin.

144. (New) The method of claim 102, wherein the composition is administered to the subject for a sufficient number of days so as to achieve a steady-state serum testosterone concentration.

B15 cont

145. (New) The method of claim 144, wherein the composition is administered for at least 7 days.

146. (New) The method of claim 144, wherein the composition is administered for at least 30 days.

147. (New) The method of claim 144, wherein the composition is administered for at least 180 days.

148. (New) The method of claim 102, wherein an amount of the pharmaceutical is administered to the subject sufficient to achieve an erection for sexual intercourse.

Sabu

149. (New) A method for improving the efficacy of a pharmaceutical useful for treating erectile dysfunction in a male subject, comprising:

percutaneously administering to the subject a pharmaceutically effective amount of a composition, comprising:

- a. about 0.1% to about 10% testosterone;
- b. about 30% to about 98% alcohol comprising ethanol, or isopropanol;
- c. about 0.1% to about 5% isopropyl myristate;
- d. about 1% to about 5% sodium hydroxide; and
- e. about 0.1% to about 5% gelling agent; and

administering the pharmaceutical to the subject;

wherein the amount of the composition administered to the subject is sufficient to achieve hormonal steady state levels of testosterone in the subject; and the percentages are weight to weight of the composition.

*B15
C111*

150. (New) The method of claim 149, wherein the subject is eugonadal.

151. (New) The method of claim 149, wherein the pharmaceutical is a phosphodiesterase inhibitor.

152. (New) The method of claim 151, wherein the phosphodiesterase inhibitor is at least one of type III, type IV, or type V, and mixtures thereof.

153. (New) The method of claim 152, wherein the phosphodiesterase inhibitor is type V.

154. (New) The method of claim 151, wherein the phosphodiesterase inhibitor is administered to the subject in about a 50 mg oral dose.

155. (New) The method of claim 151, wherein the phosphodiesterase inhibitor is administered about 20 minutes to about 60 minutes before sexual intercourse.

156. (New) The method of claim 151, wherein the phosphodiesterase inhibitor is administered in the form of at least one of a salt, ester, amide, or prodrug, and mixtures thereof.

157. (New) The method of claim 149, wherein the pharmaceutical comprises at least one of sildenafil citrate, pentoxifylline, yohimbine, apomorphine, alprostadil, papavaerine, or phentolamine, or a combination, salt, or enantiomer thereof.

158. (New) The method of claim 157, wherein the pharmaceutical is sildenafil citrate.

159. (New) The method of claim 157, wherein the pharmaceutical is apomorphine.

160. (New) The method of claim 102, wherein the pharmaceutical is administered about 20 minutes to about 60 minutes before sexual intercourse.

B15 Cmt

161. (New) The method of claim 149, wherein the composition comprises about 1.0% w/w of testosterone.

162. (New) The method of claim 149, wherein the composition comprises about 0.5% to about 1.0% w/w isopropyl myristate.

163. (New) The method of claim 149, wherein the subject is hypogadogadal.

164. (New) The method of claim 149, wherein the subject is a man, and the composition is administered to an area of skin selected from the group consisting of arm, shoulder, abdomen, back, and thigh.

165. (New) The method of claim 149, wherein the composition is administered to the subject in an amount to deliver to the skin about 25 mg to about 100 mg of testosterone per day.

166. (New) The method of claim 149, wherein the composition is administered to the skin of the subject in an amount from about 2.5 g/day to about 10.0 g/day.

167. (New) The method of claim 149, wherein the composition administered to the subject achieves a maximum serum testosterone concentration at about 16 hours to about 22 hours after administration of the composition.

168 (New) The method of claim 149, wherein in the composition is administered at least once per day.

169. (New) The method of claim 168, wherein the percutaneous administration is to same site for approximately 7 days.

170. (New) The method of claim 149, wherein the composition comprises about 0.25% to about 5% w/w testosterone.

171. (New) The method of claim 149, wherein the composition comprises about 1% w/w testosterone.

172. (New) The method of claim 149, wherein the composition comprises about 0.1% w/w testosterone.

173. (New) The method of claim 149, wherein the gelling agent comprises polyacrylic acid.

174. (New) The method of claim 173, wherein the polyacrylic acid is in an amount of about 0.9% w/w of the composition.

175. (New) The method of claim 149, wherein the composition comprises about 0.25% to about 2.5% w/w isopropyl myristate.

176. (New) The method of claim 149, wherein the composition comprises about 0.5% w/w isopropyl myristate.

177. (New) The method of claim 149, wherein the composition comprises about 40% to about 90% w/w ethanol.

178. (New) The method of claim 149, wherein the composition comprises about 72.5% w/w ethanol.

179. (New) The method of claim 149, wherein the composition and the pharmaceutical are components of a kit.

180. (New) The method of claim 179, wherein the kit further comprises a set of instructions.

181. (New) The method of claim 149, wherein the composition is the form of a gel.

182. (New) The method of claim 181, wherein the gel is in a dosage form and the dosage form weighs about 1.0 grams to about 10 grams.

183. (New) The method of claim 181, wherein the gel is in a dosage form and the dosage form weighs about 2.5 grams to about 7.5 grams.

184. (New) The method of claim 181, wherein the gel is in a dosage form and the dosage form weighs about 5.0 grams.

185. (New) The method of claim 149, wherein the testosterone comprises an enantiomer, a racemic mixture, a derivative, a base, or a salt thereof.

186. (New) The method of claim 149, wherein the composition is provided to the subject for daily administration in a 5 g, 7.5 g, or 10 g dose.

187. (New) The method of claim 186, wherein the dose delivers about 1 mg to about 100 mg of testosterone to the skin.

188. (New) The method of claim 186, wherein the dose is a 5 g dose delivering about 1 mg to about 50 mg of testosterone to the skin.

189. (New) The method of claim 186, wherein the dose is a 7.5 g dose delivering about 1 mg to about 75 mg of testosterone to the skin.

190. (New) The method of claim 186, wherein the dose is a 10 g dose delivering about 10 mg to about 100 mg of testosterone to the skin.

*B/S
Cmt*

191. (New) The method of claim 149, wherein the composition is administered to the subject for a sufficient number of days so as to achieve a steady-state serum testosterone concentration.

192. (New) The method of claim 191, wherein the composition is administered for at least 7 days.

193. (New) The method of claim 191, wherein the composition is administered for at least 30 days.

194. (New) The method of claim 191, wherein the composition is administered for at least 180 days.

195. (New) The method of claim 149, wherein an amount of the pharmaceutical is administered to the subject sufficient to achieve an erection for sexual intercourse.

196. (New) The method of claim 101, wherein the composition is the form of a gel.

197. (New) The method of claim 196, wherein the gel is in a dosage form and the dosage form weighs about 1.0 grams to about 10 grams.

198. (New) The method of claim 196, wherein the gel is in a dosage form and the dosage form weighs about 2.5 grams to about 7.5 grams.

199. (New) The method of claim 196, wherein the gel is in a dosage form and the dosage form weighs about 5.0 grams.

200. (New) The method of claim 101, wherein the testosterone comprises an enantiomer, a racemic mixture, a derivative, a base, or a salt thereof.

201. (New) The method of claim 101, wherein the composition is provided to the subject for daily administration in a 5 g, 7.5 g, or 10 g dose.

202. (New) The method of claim 201, wherein the dose delivers about 1 mg to about 100 mg of testosterone to the skin.

203. (New) The method of claim 201, wherein the dose is a 5 g dose delivering about 1 mg to about 50 mg of testosterone to the skin.

204. (New) The method of claim 201, wherein the dose is a 7.5 g dose delivering about 1 mg to about 75 mg of testosterone to the skin.

205. (New) The method of claim 201, wherein the dose is a 10 g dose delivering about 10 mg to about 100 mg of testosterone to the skin.

206. (New) The method of claim 101, wherein the composition is administered to the subject for a sufficient number of days so as to achieve a steady-state serum testosterone concentration.

207. (New) The method of claim 206, wherein the composition is administered for at least 7 days.

208. (New) The method of claim 206, wherein the composition is administered for at least 30 days.

209. (New) The method of claim 206, wherein the composition is administered for at least 180 days.

210. (New) The method of claim 101, wherein an amount of the pharmaceutical is administered to the subject sufficient to achieve an erection for sexual intercourse.